IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):	Yougandh Chitre, et al.		
Serial No.:	10/656,649	**Examiner:**	K. Schaetzle
Filed:	September 4, 2003	**Art Unit:**	3766
Docket No.:	A03P1061		
For:	MEDICAL ELECTRICAL LEAD PROVIDING FAR-FIELD SIGNAL ATTENUATION		

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

I hereby certify that this correspondence is being e-filed on:
2008-03-07
Iliana Cancino 3/7/08
Date

DECLARATION UNDER 37 CFR 1.132

I, Gene A. Bornzin, declare that:

1) I am one of the named co-inventors of the above-identified patent application, which was filed on September 4, 2003.

2) At the time of filing of our application, my co-inventors and I believed that either an active fixation embodiment with a helical cathode electrode (such as shown in Figures 1-3 of the application) or a passive fixation embodiment with a tip electrode serving as the cathode (such as shown in Figure 4 of the application) would function equivalently with regards to T-wave attenuation, so long as the inter-electrode spacing was within the claimed range of 1.0 to 3.5 mm; therefore we included Figure 4 as an alternate embodiment of the invention.

3) Subsequent to filing our patent application, we tested various configurations of leads having closely spaced electrodes, and we learned that the passive fixation embodiments did not significantly attenuate T-waves to avoid T-wave oversensing. We tested both active fixation embodiments (such as those shown in Figures 1-3) and passive fixation embodiments (as shown in Figure 4) and found that the passive fixation leads do not attenuate T-waves to the degree necessary to reliably avoid T-wave oversensing. This

was an unexpected result, as we had previously believed that either configuration would function in a similar manner with respect to T-wave sensing. The active fixation leads we tested had electrode surface areas as follows: 8 mm^2 for the helix electrode, and 17 mm^2 for the ring electrode.

4) Through this experimentation we learned that the combination of a) close inter-electrode spacing between 1.0 and 3.5 mm and b) active fixation with a helical electrode were critical to achieving T-wave attenuation for reliably avoiding T-wave oversensing. Embodiments such as that shown in Figure 4 did not work for T-wave attenuation purposes.

5) In addition to the above testing done after filing our patent application, I built and tested a lead as described in the Thompson et al. patent (a passive fixation lead including a tip electrode serving as the cathode electrode). The lead had two, independently selectable ring electrodes to alternately serve as the anode electrode: one was spaced approximately 1.0 millimeter from the tip electrode (the "test configuration") and the other was spaced approximately 10 millimeters from the tip electrode (the "standard configuration"). The tip electrode had a surface area of approximately 3.5 mm^2 and each ring electrode had a surface area of approximately 17 mm^2. In other words, the test configuration is the structure described in the Thompson et al. patent. I tested the lead in the right ventricle of a canine.

6) When using the standard configuration, the T-wave amplitude following paced ventricular events averaged approximately 3.1 mV, and for the test configuration the T-wave amplitude following paced ventricular events averaged approximately 2.8 mV (see Appendix A from my previous declaration). Therefore, there was no significant T-wave attenuation for a passive fixation lead, regardless of the inter-electrode spacing.

7) It has been brought to my attention that in the most recent Office Action from the U.S. Patent Office, the examiner contends that the evidence submitted in conjuction with my co-inventor Yougandh Chitre's declaration "compares two active fixation leads with tissue penetrating distal helical electrodes and proximal ring electrodes spaced at varying distances" and that this evidence "fails to establish that the helical tip itself provides any attenuation in T-wave amplitude". While this is true if the examiner simply looks at the evidence submitted with Mr. Chitre's declaration, when combined with the

evidence submitted with my previous declaration of October 30, 2007, in combination we have shown that a) a close inter-electrode spacing is required in order for an active fixation lead to significantly attenuate T-waves (from the evidence we supplied with Mr. Chitre's declaration) and b) passive fixation leads do not significantly attenuate T-waves, regardless of the inter-electrode spacing (from my previous declaration). Therefore, in order to significantly attenuate T-waves, a lead must have both a close inter-electrode spacing and be an active fixation lead with a helical electrode. This result was unexpected to us, as described above.

8) It has also been brought to my attention that the Patent Office examiner is unclear how one embodiment (as shown in our Figure 3) can significantly attenuate T-waves, yet a similar embodiment (as shown in our Figure 4 and the lead described in the Thompson et al. patent) cannot. As stated above, at the time of filing our patent application, I and my co-inventors believed that both embodiments would achieve the same results with respect to T-wave attenuation, but through testing we quite unexpectedly discovered that only the active fixation embodiment would sufficiently attenuate T-waves and thereby avoid T-wave oversensing.

9) The undersigned declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

5/7/08
Date

Gene A. Bornzin, Ph.D